

REMARKS

Applicant submits this Amendment in response to the Office Action mailed on October 4, 2004 and following a telephonic interview with the Examiner on October 19, 2004 and an interview with the Examiner at the Examiner's Office on December 7, 2004.

Previously pending claims 75 to 89 have not been amended. New independent claim 90 and dependent claims 91 to 93 have been added. New independent claim 94 and dependent claims 95 and 96 have been added. No new matter is added by the present amendments to the claims. Support for the new features in the claims is as follows.

Support for the feature of "spraying" in claim 90 is found in the specification on page 8, line 16. Support for the "device" in claim 90 is found on page 8, lines 15 and 16. Support for claim 91 is found on page 5, line 34. Support for claim 92 is found in Example 2 on pages 9 and 10 and specifically on page 10, lines 12 to 17. Support for claim 94 is found on page 8, lines 15 and 16. Support for claims 93 and 95 is found on pages 8 and 9, bridging paragraph.

REJECTIONS OF THE CLAIMS

I. Rejection under 35 U.S.C. §102(b)

The Examiner has rejected claims 75 to 89 as being anticipated by a practice that people often do, such as, as stated by the Examiner in the Office Action in paragraph 3 on page 2, "be in a mist environment, such as walking in a foggy morning, take a sauna bath." Applicant traverses the rejection of the claims on this ground.

Independent claims 75 and 83 call for *administering* an aqueous fluid or composition. Claims 76 to 82 depend from claim 75 and claims 84 to 89 depend from claim 82. Thus, all presently rejected claims contain this feature.

The specification, in several instances, discloses that such administering is applying a fluid to the surface of the eye. See for example, page 5, line 15, to page 6, line 8. Applicant submits that, in the context of this application, the term "administering a fluid" is synonymous with "applying a fluid". Applicant further submits that this administering, which is an action, is distinct from a person being in a mist environment, which is passive. In such an environment, an individual does not apply or administer the mist.

Accordingly, Applicant submits that the presently rejected claims, claims 75 to 89, contain a feature that is not anticipated by a practice that people do and that the rejection of these claims over such a practice is overcome. Applicant respectfully requests the Examiner to withdraw the rejection of claims 75 to 89 on this ground.

New method claims 90 to 93 call for spraying a mist from a container. Applicant submits that it is clear that the practice of being in a mist environment does not provide for spraying a mist from a container. Accordingly, Applicant submits that claims 90 to 93 patentably distinguish over the practice of being in a mist environment.

II. Rejection under 35 U.S.C. §103(a)

The Examiner has rejected claims 75 to 89 as being obvious under 35 U.S.C. §103(a) over Embleton et al (WO 97/23177) in view of Laibovitz et al (U.S. Patent No. 5,997,518). Applicant traverses the rejection of the claims on this ground.

Embleton discloses an apparatus for delivering small volumes of liquid to the eye in the form of a jet or stream of droplets. The apparatus of Embleton provides a minimum range of volume of treatment fluid to be between 3 to 8 microliters. Embleton further discloses that the ophthalmic treatment liquids that may be used with the invention include:

- 6) Artificial tear/dry eye therapies, comfort drops, irrigation fluids, etc., e.g. physiological saline, water, or oils; all optionally containing polymeric compounds such as acetylcysteine, hydroxyethylcellulose, hydroxymellose, hyaluronic acid, polyvinyl alcohol, polyacrylic acid derivatives, etc. (page 13, lines 6-12)

Laibovitz discloses an apparatus for delivering small volumes of liquid to the eye in the form of very small droplets. The invention of Laibovitz overcomes the adhesion forces that are encountered when delivering drops of liquid to the eye from droppers, such as surface tension at the tip diameter, difficulties in use, lack of control of quantity, and contamination. Laibovitz discloses that this apparatus can deliver small volumes which permits the efficient use of therapeutic medications because administration of small volumes prevents runoff of the medications with resultant wastage of medication or loss of medication into the tear duct with subsequent inhalation and entry into the systemic circulation. The device of Labovitz can deliver drops in the size of those in an aerosol or mist. See column 11, lines 32-34.

A. The Examiner has failed to establish a prima facie case of obviousness

Applicant submits that the cited prior art, either considered alone or in combination, does not disclose or suggest the present invention as called for in the claims. Neither Embleton nor Laibovitz, nor the combination of Embleton and Laibovitz, disclose or suggest the present invention of a method for moisturizing the surface of the eye by administering an aqueous formulation as called for in the claim. Moreover, neither Embleton nor Laibovitz disclose or suggest administration of an aqueous formulation to the surface of the eye in the form of a mist.

Additionally, Applicant submits that it is error to combine the disclosure of Embleton and Laibovitz to reject claims drawn to a mist as (1) Embleton teaches away from a mist and (2) Laibovitz likewise teaches away from a mist.

As discussed previously in connection with this application, Embleton discloses a jet or stream of droplets. The previous Examiner and the present Examiner have stated several times during the prosecution of this application that they see no difference between a jet or stream of droplets and a mist. In the words of the present Examiner on page 6 of the present Office Action:

The Examiner fails to see the difference between the "mist" and the stream of droplets disclosed by Embleton. They are both a mass of droplets *dispersed* in air. (emphasis added)

However, Applicant respectfully submits that the Examiner is in error. Applicant has previously provided dictionary definitions that establish that jets and streams are distinct from mists. Additionally, Applicant has defined a mist on page 6, line 10 of the specification, as being "*dispersed droplets in air*." Applicant submits that the Examiner has erroneously indicated that the jet or stream of droplets disclosed by Embleton is "dispersed" in air.

Applicant submits as an attachment herewith page 406 of Webster's New World Dictionary of the American Language, Second College Edition, Simon and Schuster (1980). According to this dictionary, the term "disperse" is defined as follows:

dis'perse *vt.* -**persed'**, -**pers'ing** . . . 1. to break up and scatter in all directions; spread about; distribute widely 2. to dispel (mist, etc.) 3. to break up (light) into its component colored rays - *vi.* to break up and move in different directions; scatter - **SYN.** see SCATTER . . .

In contrast, Embleton discloses, on page 3, lines 6 to 9 that:

The jet or stream can be directed or targeted at a chosen site in an eye; eg, cornea, anterior bulbar conjunctiva, posterior bulbar conjunctiva, or palpebral conjunctive . . .

It is evident that administration of a fluid by any method that provides for dispersed droplets cannot be targeted to the eye, much less to a chosen site in an eye. Embleton clearly teaches away from dispersed droplets in air (a mist).

Moreover, Applicant respectfully submits that, although Laibovitz discloses that his apparatus may emit droplets the size of those found in a mist, Laibovitz, like Embleton, also teaches away from a mist. In the previous Amendment, filed on January 30, 2004, Applicant erroneously cited Laibovitz, at column 14, lines 20 to 25, as noted by the Examiner in the present Office Action on page 6.

The citation to Laibovitz in that Amendment was from column 14, lines 20-25 of U.S. Patent No. 6,159,188, a continuation-in-part of the Laibovitz reference cited by the Examiner, U.S. Patent No. 5,997,518. It is well established law that the disclosure in a patent may be

interpreted in view of the disclosure in a related application. In the CIP application, Laibovitz further discusses the apparatus for delivery of fluid to the eye and states, at column 14, lines 20 to 25, in reference to mists, that:

Moreover the spray pattern of a perfume atomizer is generally greater than about two (2) inches in diameter and is therefore unsuitable for the preferred prime uses of the apparatuses of the invention which are for controlled application of extremely small quantities of drugs to the eye in less than two inch diameter patterns.

Laibovitz, like Embleton and in contrast to the assertion of the Examiner, clearly distinguishes between dispersed droplets in air (a mist) and a jet or a stream. Thus, although the Examiner fails to recognize a distinction between a mist and a jet or a stream, those skilled in the relevant art of administering liquids to the eye do indeed recognize such a distinction and both of the cited references disclose such a distinction and teach away from the use of a mist.

Accordingly, Applicant submits that all present claims that call for a mist are patentably distinguishable over the prior art and the Examiner is requested to withdraw the rejection of all such claims on this ground.

Moreover, even with regard to claims that do not call for a mist, Applicant submits that neither Embleton, Laibovitz, nor the combination of Embleton and Laibovitz disclose or suggest the present invention. Both Embleton and Laibovitz deal with the problem of overdosing a liquid containing a medicament to the eye. Such overdosing results in two deleterious effects. The first such deleterious effect is that providing a medicament in an amount of liquid that is greater than that which can be retained by the eye results in wastage of the medicament and a lack of

precision in dosage. The second and more serious deleterious defect is that providing a medicament in a too large volume of fluid to the eye results in runoff of the medicament down the tear duct and into the nasal passages where it can be inhaled into the systemic circulation of a patient, with potentially disastrous effects depending on the nature of the medicament.

Neither Embleton or Laibovitz deal with the problem of moisturizing the surface of the eye and one skilled in the art, upon reading Embleton and Laibovitz, would not understand that the quantities of fluid disclosed and claimed in the present invention, are sufficient for moisturizing the eye. Thus, the prior art does not disclose or suggest the present invention.

For these reasons, it is asserted by Applicant that the Examiner has failed to establish a prima facie case of obviousness of the claims in view of the prior art. The references fail to disclose or suggest the present invention to moisturize the surface of the eye utilizing the amounts of fluid called for in the claims and, in fact, the prior art teaches away from one of the preferred embodiments of the invention, namely a mist. Because the Examiner has failed to establish a prima facie case of obviousness, Applicant respectfully requests the Examiner to withdraw the rejection of the claims on this ground.¹

¹ The Examiner has stated, on page 5 of the Office Action, that the declarations filed on February 2, 2004 are insufficient to overcome the rejections of the claims. It is respectfully pointed out, however, that the declarations are pertinent with regards to the rejection of the claims only if the Examiner has established a prima facie case of obviousness. Applicant submits that the Examiner has failed to do so and that the claims are patentable in view of the disclosure of the prior art, even without the submission of the declarations.

B. Even if a prima facie case of obviousness has been made, the rejection is rebutted. Applicant submits that the Examiner has not established a prima facie case of obviousness and that the claims are patentable over the prior art. However, assuming that the Examiner has indeed established that the claims are prima facie obvious in view of the combined disclosure of Embleton and Laibovitz, Applicant submits that the declarations filed on January 30, 2004 are sufficient to overcome such prima facie obviousness.

The Examiner stated several reasons why he feels that the Declarations were insufficient to overcome the rejection of the claims.

A) The Examiner stated that the declarations were directed to those in need of the relief of eye symptoms and the claims are not so limited. Applicants submit that one does not moisturize one's eyes unless one is in need thereof and that this basis of rejection, therefore, is specious. However, Applicant will agree to amend the claims to include the feature that the subject administering the aqueous fluid is in need of moisturizing the eye. Applicant has included such feature in the newly added claims.

B) The Examiner stated that the declarations ignore the teachings of the cited references because one skilled in the art would not expect such a small amount of water to have a deleterious effect. Applicant respectfully submits that the prior art, Embleton, does not disclose the administration of water into the eye. Rather, Embleton discloses the following:

6) Artificial tear/dry eye therapies, comfort drops, irrigation fluids, etc., e.g. physiological saline, water, or oils; all optionally containing polymeric compounds such as acetylcysteine, hydroxyethylcellulose,

hydroxymellose, hyaluronic acid, polyvinyl alcohol, polyacrylic acid
derivatives, etc. (page 13, lines 6-12)

Applicant submits that it is clear from this disclosure that Embleton is not disclosing the administration of water. Rather, Embleton discloses artificial tear/dry eye therapies, comfort drops, irrigation fluids, etc., that are based on physiological saline, based on water, or based on oils. In the context of this paragraph in Embleton, one skilled in the art would not read Embleton to mean the application of an artificial tear, comfort drop, or irrigation fluid into the eye consisting of physiological saline. Nor would one skilled in the art read Embleton to mean the administration of an oil into the eye. Rather, it is clear that the disclosure of Embleton is directed to an artificial tear, comfort drop, or irrigation fluid based on physiological saline or on an oil. The same holds for Embleton's disclosure of water. It is clear that Embleton discloses artificial tears, comfort drops, or irrigation fluids that are based on water. Embleton does not disclose the administration of water per se.

Applicant has previously submitted a First Declaration of Rachael Garrett in which Dr. Garrett testified that:

... it is my understanding that Embleton does not disclose the use of water, per se, as an artificial tear/dry eye therapy or comfort drop. Rather, my understanding is that Embleton discloses artificial tear/dry eye therapies and comfort drops that are based upon saline, water or oil, and which include other ingredients that are necessarily present in these formulations.

Dr. Garrett further testified that, in her opinion, other eye care professionals would also understand the disclosure of Embleton as she does.

Thus, Applicant submits that the Declarations do not ignore the teachings of the cited references because the cited references do not indeed teach the administration of an aqueous fluid consisting essentially of water to the surface of the eye.

C) The Examiner stated that the declarations compared a commercial product, eye drops, and not the closest prior art.

Applicant submits that the Declarations of Dr. Darwin Liao and of Dr. William Mathers provided data to show that the method of the invention was found to be more effective and more well tolerated by users than are eye drops. Eye drops, rather than jets or streams of liquid, are routinely used to treat symptoms of eye irritation and of dry eye because eye drops are easier to use and are better tolerated than are jets of liquid which are uncomfortable and difficult to apply. Thus, the comparison of efficacy and ease of use testified to in the Declarations was between the present invention and a mode of application of fluid that is already known to be more easy to use than is the method of Embleton and Laibovitz. It is presumably for this reason that the disclosure of Embleton and Laibovitz is concerned with the localized administration of a small amount of fluid when dosing an ophthalmic medication. Eye drops provide too large a quantity of water for this purpose and the discomfort associated with a blast of a jet of liquid is not so important compared to the necessity for solving the problem of accurately dosing a medicament to the eye. Such discomfort does become a serious issue when the concern is not dosing a medicament to the eye but rather is moisturizing the eye.

Accordingly, Applicant submits that the Declarations do indeed address the closest prior art. It is noted that MPEP 716.02(e) states that the claimed invention may be compared with prior art that is closer than that applied by the Examiner. It is further noted that MPEP 716.01(b) states that indirect comparisons of the claimed invention with the closest prior art may be made. In the present case, the compared eye drops are closer in comfort and ease of use than are jets of liquid and therefore, applicant submits that the requirements for a declaration to address the closest prior art have been met.

D) The Examiner stated that the submission of the Exchange & Commissary News, 43(1):6 (January 15, 2004) affirms that the claimed invention functions as it is intended to and is not relevant to the issue of obviousness as it provides no objective evidence thereof.

Applicant submits that the Examiner is incorrect in this assessment. The submission of the Exchange & Commissary News provides secondary evidence of nonobviousness as the article provides facts to show commercial success of the claimed invention. See MPEP 716.03. In this case, the United States military is using the commercial embodiment of the invention to help troops moisturize their eyes in a very demanding situation, that of desert conditions. Applicant submits, accordingly, that this article is very strong evidence of nonobviousness.

In view of the above, Applicant respectfully requests the Examiner to reconsider and to withdraw the rejection of the claims as being obvious in view of the prior art.

III. New Claims Discussed at Interview

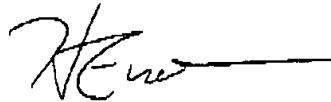
During the interview of December 7, 2004, the Examiner and the undersigned Attorney for Applicant agreed that claim 90, as submitted herewith, is not anticipated or obvious in view

of the prior art. During the interview, it was agreed that spraying a mist, as called for in the newly added claim 90, is distinct from the jet or stream disclosed in the Embleton prior art reference.

Conclusion

Applicant respectfully requests the Examiner to withdraw the rejection of the claims and to issue a notice of allowance for this application.

Respectfully submitted,



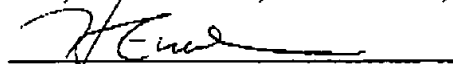
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Attachments: Webster's New World Dictionary of the American Language, Second College Edition, Simon and Schuster, p. 406 (1980)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on December 9, 2004.

Dated: 12/9/04


Howard M. Eisenberg